FDA a statement certifying that a field copy of the amendment has been sent to the applicant's home FDA district office.

(c) *Abbreviated antibiotic application.* The applicant shall comply with the provisions of § 314.60.

[57 FR 17983, Apr. 28, 1992, as amended at 58 FR 47352, Sept. 8, 1993]

EFFECTIVE DATE NOTE: At 64 FR 401, Jan. 5, 1999, § 314.96 was amended by removing paragraph (c), effective May 20, 1999.

§ 314.97 Supplements and other changes to an approved abbreviated application.

The applicant shall comply with the requirements of §§ 314.70 and 314.71 regarding the submission of supplemental applications and other changes to an approved abbreviated application.

§ 314.98 Postmarketing reports.

(a) Except as provided in paragraph (b) of this section, each applicant having an approved abbreviated new drug application under § 314.94 that is effective shall comply with the requirements of § 314.80 regarding the reporting and recordkeeping of adverse drug experiences.

(b) Each applicant shall submit one copy of each report required under § 314.80 to the Division of Epidemiology and Surveillance (HFD–730), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857.

(c) Each applicant shall make the reports required under § 314.81 and section 505(k) of the act for each of its approved abbreviated applications.

[57 FR 17983, Apr. 28, 1992, as amended at 64 FR 401, Jan. 5, 1999]

EFFECTIVE DATE NOTE: At 64 FR 401, Jan. 5, 1999, § 314.98 was amended in paragraph (a) by removing the phrase ''approved abbreviated antibiotic application under § 314.94 or'' and in paragraph (c) by removing the words ''sections 505(k) and 507(g)'' and by adding in their place the words ''section 505(k)'', effective May 20, 1999.

§ 314.99 Other responsibilities of an applicant of an abbreviated application.

(a) An applicant shall comply with the requirements of § 314.65 regarding withdrawal by the applicant of an unapproved abbreviated application and § 314.72 regarding a change in ownership of an abbreviated application.

(b) An applicant may ask FDA to waive under this section any requirement that applies to the applicant under §§ 314.92 through 314.99. The applicant shall comply with the requirements for a waiver under § 314.90.

Subpart D—FDA Action on Applications and Abbreviated Applications

SOURCE: 50 FR 7493, Feb. 22, 1985, unless otherwise noted. Redesignated at 57 FR 17983, Apr. 28, 1992.

§ 314.100 Timeframes for reviewing applications and abbreviated applications.

(a) Within 180 days of receipt of an application for a new drug under section 505(b) of the act, or of an abbreviated application for a new drug under section 505(j) of the act, FDA will review it and send the applicant either an approval letter under § 314.105, or an approvable letter under § 314.110, or a not approvable letter under § 314.120. This 180-day period is called the ''review clock.''

(b) During the review period, an applicant may withdraw an application under § 314.65 or an abbreviated application under § 314.99 and later resubmit it. FDA will treat the resubmission as a new application or abbreviated application.

(c) The review clock may be extended by mutual agreement between FDA and an applicant or as provided in §§ 314.60 and 314.96, as the result of a major amendment.

[57 FR 17987, Apr. 28, 1992, as amended at 64 FR 402, Jan. 5, 1999]

EFFECTIVE DATE NOTE: At 64 FR 402, Jan. 5, 1999, § 314.100 was amended in paragraph (a) by removing the phrase ''or of an application or abbreviated application for an antibiotic drug under section 507 of the act,'', effective May 20, 1999.

§ 314.101 Filing an application and receiving an abbreviated new drug application.

(a)(1) Within 60 days after FDA receives an application, the agency will